

Attorney Docket No. 05569.0004.DVUS11

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

McCafferty, et al.

App. No.:

10/803,622

Confirmation No.:6206

Filing Date:

March 18, 2004

Title:

Methods for Producing Members of

Specific Binding Pairs

Art Unit:

1639

Examiner:

To Be Assigned

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date

07/09/04

Date

Coddy C. Scott, Jr., Ph.D. Cegistration No. 53,573

REQUEST FOR CORRECTION TO FILING RECEIPT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sirs:

In response to the Notice Regarding Benefit/Priority Claim mailed April 28, 2004, we are enclosing herewith a copy of the Official Filing Receipt received from the U.S. Patent & Trademark Office with a correction priority claim marked in red ink.

The Notice Regarding Benefit/Priority Claim indicated that Applicant submitted a benefit claim to a prior-filed nonprovisional application and improperly indicated the prior-filed application is a national application under 37 U.S.C. 371, and requests applicant to provide evidence that the prior-filed application is a national stage application.

This application is a divisional application of U.S. Patent Application No. 09/726,219, filed November 28, 2000, which is a continuation of U.S. Patent Application No. 08/484,893, filed June 7, 1995 (now U.S. Patent No. 6,172,197), which is a continuation of U.S. Application No. 07/971,857 (the "'857 Application") which is the National Stage of PCT/GB91/01134, filed July 10, 1991 (now U.S. Patent No. 5,969,108). Enclosed herewith is a copy of the first page of U.S. Patent No. 5,969,108, which indicates that the '857 Application was a national stage application filed under 35 U.S.C. 371. Applicants submit herewith Preliminary Amendment Under 37 C.F.R. § 115 clarifying the priority claim.

Please ensure that this correction is entered, and that a Corrected Filing Receipt is mailed to our office.

Respectfully submitted,

HOWREY SIMON ABMOLD & WHITE LLP

By:_

Registration No.

Registration No. 53,573

Date: July 9, 2004

321 N. Clark Street, Suite 3400

Chicago, Illinois 60610 Tel: (312) 846-5621

Fax: (312) 595-2250



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FILING OR 371 ATTY.DOCKET NO IND CLMS ART UNIT FIL FEE REC'D **DRAWINGS** TOT CLMS APPL NO (c) DATE 1456 05569.0004.DVUS11 2 03/18/2004 1639 10/803,622

CONFIRMATION NO. 6206

HOWREY SIMON ARNOLD & WHITE, LLP

Attention: Box No. 34

1299 Pennsylvania Avenue, N.W. Washington, DC 20004-2402

FILING RECEIPT

OC00000012472520

Date Mailed: 04/28/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

John McCafferty, Sawston, UNITED KINGDOM; Anthony Richard Pope, Cambridge, UNITED KINGDOM; Kevin Stuart Johnson, Cambridge, UNITED KINGDOM; Henricus Renerus Jacobus Mattheus Hoogenboom, Cambridge, UNITED KINGDOM; Andrew David Griffiths, Cambridge, UNITED KINGDOM; Ronald Henry Jackson, Cambridge, UNITED KINGDOM; Kaspar Philipp Holliger, Cambridge, UNITED KINGDOM; James David Marks, Cambridge, UNITED KINGDOM; Timothy Piers Clackson, Palo Alto, CA; David John Chiswell, Buckingham, UNITED KINGDOM; Gregory Paul Winter, Cambridge, UNITED KINGDOM; Timothy Peter Bonnert, Cambridge, UNITED KINGDOM;

DOCKETED Smm #30/04

Assignment For Published Patent Application

Cambridge Antibody Technology Limited; Medical Research Council;

Domestic Priority data as claimed by applicant

This application is a DIV of 09/726,219 11/28/2000 which is a CON of 08/484,893 06/07/1995 PAT 6,172,197 which is a CON of 07/971,857 01/08/1993 PAT 5,969,108 which is a 371 of PCT/GB91/01134, filed July 10, 1991

DOCKET DEPT HOWREY SIMON ARNOLD & WHITE

APR 3 0 2004

Foreign Applications

WASHINGTON, D.C.

UNITED KINGDOM 9015198.6 07/10/1990 UNITED KINGDOM 9022845.3 10/19/1990 UNITED KINGDOM 9024503.6 11/12/1990 UNITED KINGDOM 9104744.9 03/06/1991 UNITED KINGDOM 9110549.4 05/15/1991

If Required, Foreign Filing License Granted: 04/27/2004

Projected Publication Date: 08/05/2004

Non-Publication Request: No

Early Publication Request: No

Title

Methods for producing members of specific binding pairs

Preliminary Class

435

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



United States Patent [19]

McCafferty et al.

Patent Number: [11]

5,969,108

Date of Patent: [45]

Oct. 19, 1999

METHODS FOR PRODUCING MEMBERS OF SPECIFIC BINDING PAIRS

| [75] | Inventors: | John McCafferty, Sawston; Anthony Richard Pope; Kevin Stuart Johnson, both of Cambridge; Henricus Renerus Jacobus Mattheus Hoogenboom, Little Shalford; Andrew David Griffiths, Cambridge; Ronald Henry Jackson, Cambridge; Kaspar Philipp Holliger, Cambridge; James David Marks, Cherry Hinton, all of United Kingdom; Timothy Piers Clackson, Palo Alto, Calif.; David John Chiswell, Middle Claydon, United Kingdom; Gregory Paul Winter; Timothy Peter Bonnert, |
|------|------------|--|
| | | |

[73] Assignees: Medical Research Council, London; Cambridge Antibody Technology Limited, Cambridgeshire, both of United Kingdom

Jan. 8, 1993

| [21] Appl. No. | : 07/971,85 |
|----------------|-------------|
|----------------|-------------|

§ 371 Date:

[22] PCT Filed: Jul. 10, 1991

[86] PCT No.: PCT/GB91/01134

§ 102(e) Date: Jan. 8, 1993

[87] PCT Pub. No.: WO92/01047

PCT Pub. Date: Jan. 23, 1992

[30] Foreign Application Priority Data

| Oct. 19, 1990 | | United Kingdom | | 9022845 |
|----------------------------|------|----------------|---------------------|----------|
| Nov. 12, 1990 | [GB] | United Kingdom | | 9024503 |
| Mar. 6, 1991 | [GB] | United Kingdom | | 9104744 |
| May 15, 1991 | [GB] | United Kingdom | | 9110549 |
| [51] Int. Cl. ⁶ | | C07K | 19/ 00 ; C07 | H 21/04; |

| | | C12N 15/13 |
|------|----------|---|
| [52] | U.S. Cl. | 530/387.3; 530/867; 435/9.1; |
| | | 435/69.1; 435/69.8; 435/320.1; 435/235.1; |
| | | 536/23 1 - 536/23 53 - 536/23 4 |

[58] Field of Search 530/387.1, 412, 530/387.3, 867; 536/23.1, 23.53, 23.4; 435/5, 252.3, 6, 69.6, 7.1, 69.7, 9.1, 69.1, 69.8, 230.1, 320.1

[56] References Cited

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

| B-27617/88 | 7/1989 | Australia | *************************************** | C12P | 21/00 |
|------------|--------|-----------|---|------|-------|
| | | | | | |

| WO 83/02393 | 7/1983 | WIPO. |
|-------------|---------|-----------------|
| WO 88/06630 | 9/1988 | WIPO C12P 21/00 |
| WO 88/09344 | 12/1988 | WIPO C07K 13/00 |
| WO 90/02809 | 3/1990 | WIPO C12P 21/00 |
| WO 90/05144 | 5/1990 | WIPO C07K 13/00 |
| WO 90/14424 | 11/1990 | WIPO C12N 15/00 |
| WO 90/14430 | 11/1990 | WIPO C12P 19/34 |
| WO 90/14443 | 11/1990 | WIPO C12Q 1/70 |
| WO 91/10737 | 7/1991 | WIPO C12N 15/13 |
| WO 91/17271 | 11/1991 | WIPO C12Q 1/70 |
| WO 92/06204 | 4/1992 | WIPO C12N 15/64 |
| WO 92/09690 | 6/1992 | WIPO C12N 15/00 |
| WO 92/18619 | 10/1992 | WIPO C12N 7/01 |
| | | |

OTHER PUBLICATIONS

Bass et al., Proteins, Structure, Function and Genetics 8:309-314 (1990).

de la Cruz et al., J. Biol. Chem. 263(9):4318-4322 (1988). Huse et al., Science 246:1275-1281 (1989).

Kang et al., Proc. Natl. Acad. Sci. USA 88:4363-4366

McCafferty et al., Nature 348:552-554 (1990).

Milstein, F.R.S., Proc. R. Soc. London B 239:1-16 (1990).

Parmley and Smith, Gene 73:305-318 (1988).

Short et al., Nucleic Acids Research 16(15):7583-7600 (1988).

Smith, Science 228:1315-1317 (1985).

Tsunetsugu-Yokota et al., Gene 99:261-265 (1991).

Winter and Milstein, Nature 349:293-299 (1991).

Kabat Sequences of Proteins of Immunological Interest 4th ed. (1987), p. 181.

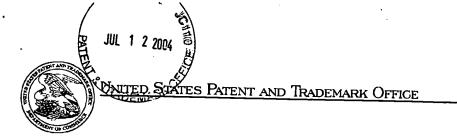
Sambrook et al. Molecular Cloning: A Laboratory Manual 4.13, 4.14, 4.17-4.19, 4.46 and A.12 (1989).

Primary Examiner-Frank C. Eisenschenk Attorney, Agent, or Firm-Marshall, O'Toole, Gerstein, Murray & Borun

[57] **ABSTRACT**

A member of a specific binding pair (sbp) is identified by expressing DNA encoding a genetically diverse population of such sbp members in recombinant host cells in which the sbp members are displayed in functional form at the surface of a secreted recombinant genetic display package (rgdp) containing DNA encoding the sbp member or a polypeptide component thereof, by virtue of the sbp member or a polypeptide component thereof being expressed as a fusion with a capsid component of the rgdp. The displayed sbps may be selected by affinity with a complementary sbp member, and the DNA recovered from selected rgdps for expression of the selected sbp members. Antibody sbp members may be thus obtained, with the different chains thereof expressed, one fused to the capsid component and the other in free form for association with the fusion partner polypeptide. A phagemid may be used as an expression vector, with said capsid fusion helping to package the phagemid DNA. Using this method libraries of DNA encoding respective chains of such multimeric sbp members may be combined, thereby obtaining a much greater genetic diversity in the sbp members than could easily be obtained by conventional methods.

59 Claims, 46 Drawing Sheets



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Sox 1450 Alexandria, Virginia 22313-1450

APPLICATION NUMBER

FILING OR 371 (c) DATE

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE

10/803,622

03/18/2004

John McCafferty

05569.0004.DVUS11

CONFIRMATION NO. 6206

Date Mailed: 04/28/2004

OC000000012472519

HOWREY SIMON ARNOLD & WHITE, LLP

Attention: Box No. 34

1299 Pennsylvania Avenue, N.W.

Washington, DC 20004-2402

Notice Regarding Benefit/Priority Claim(s)

Improper Benefit Claim(s) to Prior-Filed Nonprovisional Application(s)

The benefit claim(s) to prior-filed nonprovisional application(s) is improper because there is no specific reference for each prior-filed application that includes: (1) the identification of the prior-filed application by application number, or international application number and international filing date; and (2) a clear indication the relationship (i.e., continuation, divisional, or continuation-in-part) of the nonprovisional applications. For example, applicant should amend the specification to include a specific reference, such as "This application is a continuation of Application No. 10/---,--- filed ---." in the first sentence of the specification following the title.

Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed application(s) as required by 37 CFR 1.78. A proper relationship includes an identification of each nonprovisional application as a continuation, divisional or continuation-in-part application of the immediate prior-filed nonprovisional application for which a benefit is claimed under 37 CFR 1.78 in order to establish copendency throughout the entire chain of prior-filed applications. The specific reference must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

Timeliness: The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed. See 37 CFR 1.78(a).

Improper Benefit Claim(s) to Prior-Filed Nonprovisional Application(s)

The benefit claim(s) to prior-filed provisional application(s) is improper because the instant application was not filed within twelve (12) months from the filing date of the provisional application, and there is no indication of an intermediate nonprovisional application that is directly claiming the



benefit of the provisional application and filed within 12 months of the filing date of the provisional application. For example, applicant should amend the specification to include a specific reference, such as "This application is a continuation of Application No. 10/---,--- filed ----, which claims the benefit of U.S. Provisional Application No. 60/---,--- filed----." in the first sentence of the specification following the title.

Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed applications (including an indication of any intermediate nonprovisional application that is directly claiming the benefit of the provisional application and filed with 12 months of the filing date of the provisional application) as required by 37 CFR 1.78. The required reference must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

Timeliness: The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed during the pendency of the instant application.

☐ Improper Priority Claim(s) to Prior-Filed Foreign Application(s)

The instant application was not filed within twelve (12) months from the filing date of the prior-filed foreign application, and there is no benefit claim to an intermediate nonprovisional application filed within 12 months of the filing date of the foreign application. Applicant should review each priority claim submitted and, if appropriate, provide the proper reference to any intermediate nonprovisional application filed within 12 months of the filing date of the foreign application in compliance with 37 CFR 1.78, or delete the priority claim. The required reference to an intermediate nonprovisional application must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

Timeliness: The required reference for the benefit claim to an intermediate nonprovisional application must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed.

Benefit Claims to More Than 400 Prior-Filed Applications

The Office's automated system to record and capture benefit claims is only capable of recording benefit claims for 400 prior-filed applications. Therefore, the Office is unable to generate a filing receipt containing benefit claims for more than 400 prior-filed applications even though applicant is entitled to submit benefit claims for more than 400 prior-filed applications. Accordingly, applicant should not request a corrected filing receipt to include benefit claims for more than 400 prior-filed applications.

Prior-Filed Nonprovisional Application has been Improperly Indicated as a National Stage (35 U.S.C. 371) Application

Applicant submitted a benefit claim to a prior-filed nonprovisional application and improperly indicated that the prior-filed application is a national stage application under 35 U.S.C. 371. The Office's records show that the prior-filed application is an application filed under 35 U.S.C. 111(a). The Office has entered the benefit claim to the prior-filed application as a benefit claim to an application filed under 35 U.S.C. 111(a). Any request for a corrected filing receipt to include the indication that the prior-filed application is a national stage application will not be granted unless applicant supplies evidence that the prior application was in fact a national stage application. Accordingly, applicant should not submit such request without such evidence. Applicant should submit an amendment (or an application data sheet (ADS) if the benefit claim was submitted in an ADS) to delete the indication that the prior-filed application is a national stage application.

For more information and examples on benefit claims, please see <u>Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. 119(e)</u>, 120, 121, and 365(c), 1268 <u>Off. Gaz. Pat. Office</u> 89 (March 18, 2003), which is available on the USPTO website at http://www.uspto.gov/web/offices/com/sol/og/2003/week11/patbene.htm, and the Manual of Patent Examining Procedure (MPEP) §§ 201.11 and 201.14.

PART 2 - COPY TO BE RETURNED WITH RESPONSE